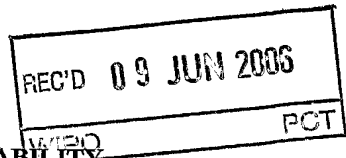


# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 1430/17 PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416																								
International application No. PCT/US04/39535	International filing date (day/month/year) 24 November 2004 (24.11.2004)	Priority date (day/month/year) 25 November 2003 (25.11.2003)																								
International Patent Classification (IPC) or national classification and IPC IPC: A61K 48/00( 2006.01) USPC: 514/44																										
Applicant ARGOS THERAPEUTICS, INC.																										
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ____ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>			<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand 15 March 2005 (15.03.2005)	Date of completion of this report 11 May 2006 (11.05.2006)																									
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer  Kimberly Chong Telephone No. 571-272-0564																									

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☒ the description:  
pages 1-48 as originally filed/furnished  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the claims:  
pages 49-53 as originally filed/furnished  
pages\* NONE as amended (together with any statement) under Article 19  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the drawings:  
pages 1-7 as originally filed/furnished  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/figs NONE
- ☒ the sequence listing (*specify*): NONE
- ☒ any table(s) related to the sequence listing (*specify*): NONE

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

*\* If item 4 applies, some or all of those sheets may be marked "superseded."*

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/39535**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. Statement

Novelty (N)	Claims <u>1-45</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>5, 19, 38-39</u>	YES
	Claims <u>1-4,7-18,20-37 and 40-45</u>	NO
Industrial Applicability (IA)	Claims <u>1-45</u>	YES
	Claims <u>NONE</u>	NO

## 2. Citations and Explanations (Rule 70.7)

Claims 1-4, 7-18, 20-37, 40-45 lack an inventive step under PCT Article 33(3) as being obvious over Nair et al. in view of Xu et al. Nair et al. teach a method of transfection an antigen presenting dendritic cell with at least on mRNA (see column 8, lines 58-68). Nair et al. does not teach transfection the antigen presenting cell with a sense oriented mRNA and a method of generating sense oriented mRNA. Xu et al. teach a method of generating and amplifying sense strand mRNA using a T7 promoter from any biological sample (see Figure 2 and paragraph 0023).

It would have been obvious to one of ordinary skill in the art at the time invention was made to make sense oriented mRNA as taught by Xu et al. and use in the method of transfection antigen presenting cells as taught by Nair et al.

Claims 5, 19 and 38-39 meet the criteria set out in PCT Article 33(2) and (3), because the prior art does not teach or fairly suggest the claimed invention.

One would have been motivated to use the amplified sense oriented mRNA as taught by Xu et al. because Xu et al. teach sense oriented mRNA prepared using this method provides a higher quality mRNA population of sequences that are more representative of the mRNA population pool for the original sample. Additionally, one would have been motivated to use this sense oriented mRNA in the method to transfect because the method taught by Xu et al. provides a high quality RNA that is more representative of the sample RNA that would be useful for a vaccine or therapeutic as taught by Nair et al.

Finally, one would have had a reasonable expectation of success because Xu et al. teach successful generation and amplification of sense oriented mRNA and Nair et al. teach an efficient method of transfection of antigen presenting cells using said transcribed RNA.

Thus, the invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-45 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because subject matter claimed can be made or used in industry.